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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,366	12/09/2003	Carmelita G. Frondoza	03409-PA-DIV	4407

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EXAMINER
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MAKAR, KIMBERLY A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,366	<b>Applicant(s)</b> FRONDOZA ET AL.	
	<b>Examiner</b> Kimberly A. Makar	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 54-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 54 is/are rejected.
- 7) ☒ Claim(s) 55-57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

1. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).
2. The disclosure of the prior-filed application, Application No. 09/825,632 now US Patent No. 6,886,568, application 09/712,662 now US Patent No. 6,637,437, and application 09/275,319 now US Patent No. 6,378,527, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claims 36-38, and 54-57 read on a method of replacing a tissue or body part comprising the following steps 1) preparing a solid implant; 2) preparing an injectable cell containing formulation; 3) implanting the solid implant; and 4) injecting the cell containing formulation between the tissue and the solid implant. This method, which requires all 4 steps is not supported in the previously mentioned applications. They aforementioned applications disclose the methodology for the application of the solid implant OR the application of the injectable formation, not the two together. Thus priority for claims 36-38, and 54-57 stem from application 09/922,909 now US Patent No. 6,662,805, which has a priority date of 08/06/2001.

***Response to Restriction Requirement***

3. Applicant's election without traverse of group II in the reply filed on 07/27/06 is acknowledged.
4. Claims 1-35, 39-53, and 58-70 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/27/06.
5. Acknowledgment is made that Claims 1-35, 39-53, and 58-70 have been cancelled by applicant in the reply filed on 07/27/06.

***Claim Objections***

6. Claim 54 is objected to because of the following informalities: Claim 54 misspells the word microcarrier as "micro carrier" on line 7 of the claim. Appropriate correction is required.
7. Claim 55 is objected to because of the following informalities: Claim 55 states "the implant of claim 54" when claim 54 is a method claim. Appropriate correction is required.
8. Claim 56 is objected to because of the following informalities: Claim 55 states "the implant of claim 55" when claim 55 is a method claim. Appropriate correction is required.

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9. Claim 57 is objected to because of the following informalities: Claim 55 states "the implant of claim 54" when claim 54 is a method claim. Appropriate correction is required.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

11. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

12. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 36-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, and 6-7 of U.S. Patent No. 6,662,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the method of US Patent No. 6,662,805 comprises 1) preparing a solid cell-containing implant 2) preparing a cell-containing injectable formulation 3) coating the surface of a cavity to be filled with the injectable

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formulation and 4) inserting the solid cell containing implant into the cavity that has been filled with the injectable cell-containing cavity which differs from the method of claims 36 and 38 of the instant application which comprises a method of preparing a solid implant, preparing a injectable cell-containing implant ; 3) inserting the solid implant into the cavity to be filled; and 4) injecting the cell containing formulation between the solid implant and the cavity, which simply reverses the order of the application of the implants. It would be obvious to reverse this order in certain situations, such as when a cavity has an extremely course surface, and the fluid cell containing formulation needs to be applied first, compared to other cavities where the surface is relatively smooth, and the injectable implant is more of a space-filler between and imperfectly made solid implant. A skilled artisan would have been motivated to reverse the order of the application of the implants from liquid implant followed by solid implant of U.S. Patent No. 6,662,805, to solid implant followed by liquid implant because there are some cavities where the fluid implant would play a more important role in filling the cavity, compared to other cavities, where the solid implant might make up a larger constituent of the implant. It would have been obvious to the skilled artisan to improve the method of U.S. Patent No. 6,662,805 by reversing the order of the application of the injectable implant and the solid implant in order to account for the variety of situations for which the method would be applicable.

***Claim Rejections - 35 USC § 112***

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 38 and 54 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 38 recites the limitation "the cells". There is insufficient antecedent basis for this limitation in the claim.

17. The term "substantially shorter than the first time period" in claim 54 is a relative term which renders the claim indefinite. The term "substantially shorter than the first time period" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure teaches that the first time period of culturing cells for the solid implant up to 30 days (see example 1). The disclosure further teaches that the culturing of the cells for the fluid carrier ranges from 14-21 days (see example 2) but that culturing cells seeded onto the microcarrier particles for the second time period can also be as short as 2-4 hours (see page 6, lines 4-6 of the instant specification). The specification provides no details on what "substantially shorter than the first time period" is or at what point the cells in the second time period will be ready for implantation, given the broad range (2-4 hours, through 14-21 days that is disclosed in the specification). A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

18. The term "substantially solid form" in claim 54 is a relative term which renders the claim indefinite. The term "substantially solid form" is not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not specify or define how solid is solid, and what properties distinguish a solid state from a substantially solid state. A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

19. The term "substantially fluid state" in claim 54 is a relative term which renders the claim indefinite. The term "substantially fluid state " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not specify or define how fluid is fluid, and what properties distinguish a fluid state from a solid state. A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

#### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM/09/16/06

  
DAVID GUZO  
PRIMARY EXAMINER